RECRUITMENT E-MAIL FOR COHORT D
LIGOCYTE STUDY LV03-104
12 August 2011

What is this study about?

In this study, we are testing a **vaccine against norovirus, a virus that causes vomiting and diarrhea. The vaccine is given by an injection ("a shot") in the muscle of your arm.** This vaccine is called the **IM Norovirus Bivalent VLP Vaccine** and it is an **investigational vaccine.** This means that it is still being tested and is not approved for sale in the United States by the U.S. Food and Drug Administration. **Currently 48 volunteers have received this vaccine with no significant side effects related to the vaccine.** Our main goals are:

1) to find the side effects of giving IM Norovirus Bivalent VLP Vaccine in the muscle of the arm; and
2) to study the body's responses to the vaccine.

What is Norovirus?

Norovirus is one of the most frequent causes of diarrhea. Illness can be severe and includes primarily vomiting and diarrhea. According to the Centers for Disease Control, 23 million cases of norovirus occur each year in the U.S. alone. These viruses are also a common cause of outbreaks in developing parts of the world, where diarrhea is a leading cause of death in young infants. Older populations living in nursing homes and assisted living facilities are at a risk of norovirus as well. This is similar to what is seen in cruise ships or in deployment settings. There is currently no vaccine licensed to prevent norovirus.

What is required to participate in the study?

Healthy adults between the **ages of 18 and 49** are asked to participate in this study. You will be scheduled for a **screening visit** and if you qualify and agree to participate in the vaccination, you will be scheduled for the first of two vaccinations.

In order to qualify:

- You must be willing and able to understand what will be required of you.
- You must sign the informed consent form.
- You must be in **good health** as determined by medical history, physical examination, and other testing.
- **Female subjects** must be of non-childbearing potential, or if of childbearing potential (as determined by the study doctors) ***must practice abstinence or use an effective licensed method of birth control for 30 days prior to the first injection and must agree to continue such precautions during the study and for 60 days after the second study injection.***
- **Male volunteers** must agree ***not to father a child from the first injection until 60 days after the last study injection*** and must agree to practice abstinence or to use precautions as noted above.

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How will I be compensated?

You will be compensated for your time and travel.

- **Civilian/Off-duty Military**
  - $25 for screening visit – 1 total
  - $25 for each completed visit not involving vaccination or labwork – 1 total
  - $100 for each outpatient clinic visit w/lab work or vaccination – 8 total
  - $25 for referring another volunteer into study

  Total (including screening): **up to $875**

- **On-Duty Military Volunteers**
  - $25 for screening – 1 total
  - $50 for each visit with a blood draw -- 8 total
  - $0 for each injection – 2 total
  - $0 telephone visit – 1 total

  Total (including screening): **up to $425.00**

If you are withdrawn from the study for any reason you will be compensated for all completed visits and calls. You must not participate in another study with an experimental product during the study or for one year after the second shot.

What happens during the Screening Visit?

The screening visit will include **medical history, physical examination with vital signs** (blood pressure, pulse, temperature and respirations) **and weight, and blood tests.** You will be asked to give less than 2 tablespoons of blood. You will also be asked to **report any medications,** including over the counter medications and contraceptives that you are currently taking and have taken recently. Less than ½ teaspoon of blood will be taken for **pregnancy testing of females of child-bearing potential 14 days prior to receipt of the first study injection.** Urine pregnancy tests will also be performed within one day of each planned shot and the shot will not be given if you are pregnant.

What happens during the Study Period?

If you are eligible and decide to participate, you will be **randomized (by chance like flipping a coin) to receive the vaccine dose or a placebo. The placebo is saline and is diluted saltwater.** The time of your clinic visits for vaccination will be about 2 hours. **You will receive a shot on Day 0 and on Day 28.** The study shot will be given with a needle in the muscle of your upper arm. You will have your vital signs (temperature, blood pressure) taken before each shot. You will remain in the clinic for 30 minutes after each shot for observation.
Also, on Day 0 you will have blood taken (about 1 tablespoon) and a small amount of saliva measured to determine how susceptable you are to norovirus. **You will be asked to return to the clinic on Day 7, Day 21, Day 28 (2nd study injection), Day 35, Day 56, Day 180, and Day 393 for follow-up.** A **telephone follow-up**

will also be done on Day 265. The study will require additional blood to be taken from you on Days 7, 21, 28, 35, 56, 180 and 393 to determine whether you have made anti-norovirus antibodies in your blood. The duration of the clinic follow-up visits will be about 30-45 minutes. The follow up phone call will take about 10 – 15 minutes.

What should I expect after vaccination?

The vaccine and placebo (are given by a shot with a needle into the muscle in your upper arm. **Serious complications resulting from this type of shot are rare** but include infection, nerve injury, bleeding, skin discoloration, and scarring. **After injection, pain, tenderness, swelling, redness or bruising may occur at the injection site.** Fainting may occur following injection into the muscle particularly in young adults.

An allergy to the vaccine is also possible. An allergic reaction could include skin rash, difficulty breathing, or wheezing, a sudden drop in blood pressure, a fast pulse, swelling around the mouth, throat, or eyes, and sweating. An allergic reaction may be life threatening. Because of these possible reactions, you will be closely observed after each shot.

The most common symptoms (adverse reactions) of vaccines containing similar products are pain, redness and swelling at the injection site as well as fatigue (tiredness), headache, muscle aches, joint pain, and stomach symptoms.

How do I schedule a visit and find out more information?

Please call the Clinical Trials Center using the contact information below and provide the following information to the staff:
Name
Date of Birth
Gender – M or F
Address
Phone number

Department of Clinical Trials, 6 am – 2:30 pm,
Monday - Friday at 301-319-9660

You may have your information stored in a database if you wish to be contacted for future studies